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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,358	09/11/2003	Michael Croft	051501-0305443	6765

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EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,358	CROFT ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 20 May 2005.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-76 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-39 and 69-76, drawn to a method of inhibiting or reducing a recall immune response comprising administering an agent that reduces or inhibits OX40 or OX40L signaling, expression or activity, classifiable in class 514, subclass 2.

II. Claims 40-68, drawn to a method of identifying an agent that reduces or inhibits a recall immune response, classifiable in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group I is drawn to method of inhibiting or reducing a recall immune response comprising administering an agent that reduces or inhibits OX40 or OX40L signaling, expression or activity. The invention of group II is drawn to a method of identifying an agent that reduces or inhibits a recall immune response. In the instant case the different inventions are not disclosed as capable of use together and have different functions and effects. The invention of group I functions to provide a treatment

by inhibiting or reducing a recall immune response and has the effect of inhibiting or reducing a recall immune response. The invention of group II functions to identify agents that can be used in a method of inhibiting or reducing a recall immune response and has the effect of identifying those agents.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, prior art searches of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, searches of the distinct method steps related to administration that would be required by the method of inhibiting that would not be required by the claimed assay method. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of the inventions of groups I and II together.

3. Group I is further restricted as follows:

4. Group I comprises claims to the following patentably distinct inventions. Group I comprises claims drawn to methods of treatment comprising administering a molecule that binds to OX40 or OX40L that is an: a) OX40 antibody; b) OX40L antibody; c) a modified OX40; d) a modified OX40L; e) an antisense nucleic acid molecule that binds OX40; f) an antisense nucleic acid molecule that binds OX40L; g) an RNAi that binds OX40; h) RNAi that binds OX40L and i) a cytokine. Each of these methods is

patentably distinct because each requires the use of an agent that is biologically, functionally, structurally and/or chemically distinct and that is distinguished, each from the other, by mode of operation. Each agent that is a modified OX40 or OX40L or an OX40 or OX40L antibody, antisense, RNAi or that is a cytokine, will operate based on the particular structure and activity of that chemical class of compound, will be directed to either OX40 or a ligand of OX40 (which are compounds of different structure and activity) and will not have the same mode of operation as any of the other classes listed. Antibodies operate by specific binding to antigenic sites, modified proteins can operate by competitive inhibition, antisense operates by recruiting RNase H to degrade mRNA transcripts, RNAi operates by activation of the RNA interference response thru the mechanism of the RISC complex, cytokines operate by binding cognate receptors in particular signaling pathways. If Applicant chooses to elect group I, Applicant should elect the subject matter of the invention identified as a-i, above. The claims of the elected group will be examined insofar as they read on the elected subject matter that is identified above in a-i.

5. Group II is further restricted as follows:

6. Group II comprises claims to the following patentably distinct inventions. Group II comprises claims drawn to assay methods of identifying agents that will reduce or inhibit a recall immune response comprising providing a test agent that will inhibit signaling, expression or activity of OX40 or OX40L wherein the test agent is an: j) OX40 antibody; k) OX40L antibody; l) a modified OX40; m) a modified OX40L; n) an

antisense nucleic acid molecule that binds OX40; o) an antisense nucleic acid molecule that binds OX40L; p) an RNAi that binds OX40; q) RNAi that binds OX40L and r) a cytokine. Each of these methods is patentably distinct because each requires the use of a test agent that is biologically, functionally, structurally and/or chemically distinct and that is distinguished, each from the other, by mode of operation. Each test agent that is a modified OX40 or OX40L or an OX40 or OX40L antibody, antisense, RNAi or that is a cytokine, will operate based on the particular structure and activity of that chemical class of compound, will be directed to either OX40 or a ligand of OX40 (which are compounds of different structure and activity) and will not have the same mode of operation as any of the other classes listed. Antibodies operate by specific binding to antigenic sites, modified proteins can operate by competitive inhibition, antisense operates by recruiting RNase H to degrade mRNA transcripts, RNAi operates by activation of the RNA interference response thru the mechanism of the RISC complex, cytokines operate by binding cognate receptors in particular signaling pathways. If Applicant chooses to elect group II, Applicant should elect the subject matter of the invention identified above as j-r. The claims of the elected group will be examined insofar as they read on the elected subject matter that is identified above in j-r.

7. Claim 1 link(s) inventions of group I that are identified in section 4 above as a-i. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Claim 8 link(s) inventions of group I that are identified in section 4 above as a-d. The restriction requirement among the linked inventions is

subject to the nonallowance of the linking claim(s), claim 8. Claim 12 link(s) inventions of group I that are identified in section 4 above as e-h. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 12. Claim 40 link(s) inventions of group II that are identified in section 6 above as j-r. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 40. Claim 45 link(s) inventions of group II that are identified in section 6 above as j-m. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 45. Claim 48 link(s) inventions of group II that are identified in section 6 above as n-q. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 48. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Claim 10 is generic to a plurality of disclosed patentably distinct species comprising modified OX40 or OX40L that can be subsequences, variant sequences, chimeric sequences or dominant negative sequences of either OX40 or the OX40L (ligand). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 25 and 26 are generic to a plurality of disclosed patentably distinct species comprising the symptoms listed in claims 25 and 26. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 28 is generic to a plurality of disclosed patentably distinct species comprising the interleukins listed in claim 28. If Applicant elects the species of symptom that is increased Th2 cytokine production as set forth in claim 26, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 52, 55, 57 and 58 are generic to a plurality of disclosed patentably distinct species comprising the symptoms listed in claims 52, 55, 57 and 58. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

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